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COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the Transport of Dangerous Goods
(Twentieth session, 3-12 December 2001, agenda item 10)

MISCELLANEOUS PROPOSALS OF AMENDMENTS TO THE MODEL REGULATIONS ON THE TRANSPORT OF DANGEROUS GOODS

Insertion of a new note concerning the exemption of pharmaceutical products ready for use

Transmitted by the observer from Switzerland

INTRODUCTION

Pharmaceutical products may contain dangerous components in quantities sufficient to require their classification for transport, when shipped in bulk. They are then packed and labelled like any other preparation containing hazardous components. Types of such products may be e.g.:

- Preparations containing toxic substances of Class 6.1;
- Solids or liquids containing environmentally hazardous substances of Class 9;
- Solutions for injection containing flammable liquids of Class 3;
- Emulgels containing flammable cosolvents e.g. isopropanol.

However, the same pharmaceutical products "ready for use" pose little or no danger when packed in packagings of a type as intended for retail sale or distribution.

Shipments of this kind by more than one mode of transportation cause some problems due to the lack of harmonization of the different transport regulations. The notes in **RID/ADR** for Classes 3 and 6.1, SP 601 state that "pharmaceutical products ready for use, e.g. cosmetics, drugs and medicines, which are substances manufactured and packed in packagings of a type intended for retail sale or distribution for personal or household consumption, which otherwise are substances of UN 3248 or UN 3249, are not subject to the provisions of RID and ADR." No other exemptions are provided for other UN Numbers nor other classes. Furthermore, it is not clear whether medicines for *animals* are included in this statement.

The **ICAO** Technical Instructions or the **IATA** Dangerous Goods Code for air transport offer only the positions *Medicine n.o.s.* (max. 5 kg) or *Consumer Commodity* (max. 25 kg).

The **IMDG** Code for sea transport provides no corresponding exemptions at all.

Proposal

The following amendments to the Model Regulations are proposed:

Amend paragraph 1.1.1.2 by adding a new subparagraph "(d):

d) “Pharmaceutical products ready for use, e.g. cosmetics, drugs and medicines for humans and animals, which are substances manufactured and packed in packagings of a type for retail sale or distribution for personal or household consumption and which otherwise are substances of classes 2, 3, 4.1, 4.2, 4.3, 5.1, 6.1, 8 or 9, respectively, are not subject to the provisions of the Model Regulations."